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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.								
10/675,254	09/30/2003	Hikaru Matsuda	49288.0800	2567								
7590 Charles F. Hauff, Jr. Snell & Wilmer L.L.P. One Arizona Center Phoenix, AZ 85004-2202		12/27/2006	<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">MERCIER, MELISSA S</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td colspan="2">1615</td></tr></table>		EXAMINER		MERCIER, MELISSA S		ART UNIT	PAPER NUMBER	1615	
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SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE									
3 MONTHS		12/27/2006	PAPER									

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/675,254

Applicant(s)

MATSUDA ET AL.

Examiner

Melissa S. Mercier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 6-10, 14-17 and 43-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6-10, 14-17 and 43-59 is/are rejected.
- 7) ☒ Claim(s) 17, 45, 47-59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 11, 2006 has been entered. Amendments filed on October 11, 2006 after the filing of the RCE have been entered. Claims 1, 4, 6-10, 14-17, and 43-59 are pending in this application. Claims 1, 4, 6-10, 14-17, and 43-59 are rejected.

Applicants' arguments, filed October 11, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claims 17 and 47-59 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1, 4, 6-16, and 43-46. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 17

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differs from claim 1 only in the recitation of "a subject in need thereof". It is the examiners position that this is an inherent limitation of Claim 1.

Claim 45 objected to because of the following informalities: the claim recites the limitation regeneration and/ox implantation. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has introduced new matter in the claims by the addition of "a subject in need thereof" in place of "organ". Applicant is required to remove the new matter in response to this office action. Applicants have argued the support for the new patient population can be found on page 24, lines 19-20, and page 34, lines 19-20. It is the examiners position that the cited passages do not provide support for a subject in need thereof, but rather for the administration of the biological material to a patient. Applicants are therefore requested to clearly state for the record that this disclosure inherently possesses the limitation of the instant claim.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 4, 16-17, and 47-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45 and 58 provide for the use of a cell, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Regarding Claims 4 and 47, it is unclear to the examiner what velocity of being claimed. The recitation of "less than" together with "about" is unclear. It is the Examiners position that 11, 12, 13.... is about 10. It is suggested that applicant amend the Claims to recite "equal to or less than 10ml/min".

Regarding Claims 14 and 53, it is unclear to the examiner what "substantially zero" is. The applicant has not defined the term, nor has the specification provided any guidance for the examiner to interpret the full scope of the term.

Regarding Claims 16 and 55, it is unclear to the examiner what "a heart disease" would encompass. The examiner is interpreting this limitation to include anything related to the heart, including any disease that could have an impact on the heart or heart muscle.

Claim Rejections - 35 USC § 101

Claims 45 and 58 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6-10, 14-17, and 43-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haim et al. (WO 99/39624) in view of Edge (US 6,673,604).

Haim discloses an apparatus for intra-cardiac drug delivery (abstract). The device can deliver a dose of a biological material, such as growth factor, at a determined range of velocity to the heart (abstract and Claim 45). According to Haim, the therapeutic agent can be delivered to the heart in a manner that is responsive to physiological signals (Claim 45). On the basis of the physiological signals, it is the examiner's position that one of ordinary skill in the art would have the ability to modulate the rate of drug administration on the basis of the particular application. As such, it is the examiner's position that an ordinary practitioner would have the ability to accelerate or maintain the release of the drug on the basis of evolving physiological signals. It is also the examiner's position that an ordinary practitioner would be able to modify the tip tube of the to between 0.1 mm to about 30 mm on the basis of the particular size of the heart or organ to be injected.

Haim does not teach a method of injected cells into an individual at a predetermined rate.

Edge discloses a method of injecting cells into a heart (abstract and Example 1). According to Edge, it is advantageous to inject muscle cells into a heart because said muscle cells can aid in cardiac repair (abstract). Because muscle cells, when injected into a heart, can advantageously aid in cardiac repair, one of ordinary skill in the art would have been motivated to inject cardiac cells into a heart in a manner consistent with the disclosure of Haim. Based on the teachings of Edge, there is a reasonable expectation cardiac cells, when injected into a heart, can aid in cardiac repair. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject cells, in a manner consistent with the method advanced by Haim, into a heart.

It is the examiners position that claims 43-46 and 55-59 are functional or intended use limitations. Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 105 USPQ 233,235 (CCPA 1955).

Response to Arguments

Applicant's arguments filed October 11, 2006 have been fully considered but they are not persuasive. Applicants argue the Haim reference does not teach a method of injecting cells to maintain their biological activity by controlling velocity. It is the examiners position that the Haim reference discloses a method for injecting a liquid

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drug containing cells into a heart. The recitation of "to maintain their biological activity" is a functional limitation; therefore it is the examiners position that the method taught by Haim would meet the limitation. The burden is therefore shifted to applicant to show a patentable distinction.

Applicant further argues "the Edge reference only teaches altering the parameters of flow rate, acceleration and deceleration to reduce patient discomfort when injection fluid enters the tissue (column 6, lines 15-16), but not to maintain the biological activity of an injected cell by preventing cell damage by controlling of velocity. In other words, the controlling of velocity in order to maintain biological activity of an injected cell is not taught by the Edge reference". Again, it is the examiners position that the recited limitation of "to maintain the biological activity of an injected cell" is a functional limitation and the disclosure of Edge would inherently encompass the claimed limitation.

Claims 1, 4, 6-10, 14-17, and 43-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5,690,618) in view of Edge (US 6,673,604).

Smith discloses electronic syringe compositions capable of delivering active agents, such as anesthetics, insulin, vitamins, minerals, pharmaceuticals, and imaging dyes to individuals (abstract and column 8, lines 61-64). Like the instant claim set, Smith teaches a method for delivering the active agents at a predetermined rate that may include acceleration/deceleration patterns (column 8, lines 45-54). Depending on the type of syringe used, the flow rate and needle exit velocity can be varied (column 6, lines 14- 42). For example, when a 30-gauge needle is used (an inner diameter of

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0.25 mm - See US 6,273,715; column 4, lines 59-67), the flow rate is 0.12 mils or 7.2 ml/minute (Table 1). This flow rate is well within the range of the instant claims 1 and 17.

Smith does not disclose injecting cell-based pharmaceuticals into the heart of a subject.

Edge discloses a method of injecting cells into the heart (abstract and Example 1). According to Edge, it is advantageous to inject muscle cells into a heart because said muscle cells can aid in cardiac repair (abstract). Because muscle cells, when injected into a heart, can advantageously aid in cardiac repair, one of ordinary skill in the art would have been motivated to inject cardiac cells into a Heart in a manner consistent with the disclosure of Smith. Based on the teachings of Edge, there is a reasonable expectation cardiac cells, when injected into a heart, can aid in cardiac repair. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject cells, in a manner consistent with the method advanced by Smith, into a heart.

Response to Arguments

Applicant's arguments filed October 11, 2006 have been fully considered but they are not persuasive. Applicant argues "With regard to the Examiner's assertion that it would have been obvious to those skilled the art to inject cells in a manner consistent with the method of Smith, Applicants assert that the flow rate disclosed in Smith is meant to reduce the discomfort of patients when syringes are used to inject active agents into these patients (column 6, lines 14-26 of US Patent 5,690,618). On the

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contrary, the claimed predetermined range of velocity of "at least about 1 ml/min and less than, or equal to about 20 ml/min" (emphasis added) is designed to maintain the viability or activity of the cells. As such, the skilled artisan attempting to conceive the claimed invention through the disclosure of Smith would not have been effectively instructed to maintain the activity of the cells. Therefore, Applicants assert that the claimed invention is unobvious over Smith in light of Edge. The viability or activity of the cell as claimed is again, considered to be a functional limitation. The cited references do not disclose the flow rate disclosed would damage or alter the activity of the cells at the cited ranges, therefore, it is the examiners positions that such preservation of activity would be inherently preserved.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

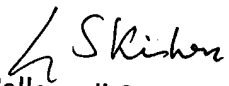
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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